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10/815,109	03/30/2004	Deepak Bhalchandra Salunke	B-5412 621815-6	6575

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/815,109

Applicant(s)

SALUNKE ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## First Office Action on the Merits

### Claim Rejections - 35 USC § 101

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-6 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 11/089,451. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 7-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-12 of copending Application No. 11/089,451. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both recite the production of a steroidal dimer by reacting an N-succinimidyl ester solution of bile acids with a polyamine. The difference between the claims is in the recitation of the polyamine, i.e., a triamine as recited by the instant claims or a diamine as recited by the copending application. However, it would be obvious to the skilled artisan that the polyamine utilized would determine the linker between the two moieties of bile acid. Therefore, the claimed process would be prima facie obvious in view of the copending application and the level of skill of the ordinary artisan in the art at the time of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 2-6 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is

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proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Note: Recitation of various properties and/or concentration of the claimed compound do not further limit the scope of the claimed invention.

6. Claim 8 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 7. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Note: Claim 7 discloses the production of cholic and deoxycholic dimers and, thus, the "N-succinimidyl esters of bile acids" recited in said claim can only refer to "cholic acid or deoxycholic acid" as recited by claim 8.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are (1) the nature of the invention, (2) the breadth of the claims, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the amount of guidance or direction presented, (6) the presence or absence of working examples, (7) the relative skill in the art and (8) the quantity of experimentation necessary. When the above factors are taken into consideration, the examiner's position is that one skilled in the art could not perform the invention commensurate in scope with the instant claim without undue experimentation.

The instant claim is drawn to treatment of all fungal infections utilizing the claimed compounds. The present specification discloses the claimed compounds have antifungal activity against *Candida albicans*, *Benjaminiella poitrasii* and *Yarrowia lipolytica* fungi. However, one cannot extrapolate the teachings of the present specification to the scope of the instant claim because the art does not teach treatment of all fungal infections utilizing a single compound. Thus, in order to practice the claimed invention commensurate in scope with the instant claim, the skilled artisan would have to test the claimed compounds against every fungi, known and unknown. In light of the quantity of experimentation necessary and the state of the prior art, it would require undue experimentation for the skilled artisan to practice the invention as broadly claimed.

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9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language of the instant claims is indefinite for the following reasons:

Claim 1 (a) lacks a period at the end and (b) recites diethylenetriamine compounds but the structures shown in the instant claim contain an ethylenediamine linker. Therefore, the claimed invention is indefinite. For the purpose of prior art rejection, the instant claim is examined as drawn to compounds as depicted by formulae 1 and 2 as recited by the instant claim and the present specification.

Claim 2 recites an "amphiphilic topology as shown in figure (3)". However, a claim cannot depend on the specification to give definition to the claimed invention and, thus, the recitation of "figure (3) in the instant claim makes it indefinite. It is also noted that the structure, i.e., figure (3), shown below is not part of claim 2 since the claim ends before said structure.

Claims 7-10 recite the production of diethylenetriamine steroidal dimers. As with claim 1, the structures depicted by the instant claims show ethylenediamine dimers and, thus, the instant claims are examined as drawn to compounds as depicted by formulae 1 and 2 as recited by the claim 7 and the present specification.

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Claim 9 recites the phrase "such as" which renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 12 and 13 are method of treatment claims which are dependent on claim 10, a method of making claim. Therefore, the instant claims are indefinite.

Claims 11-13 recite the treatment of fungal infections without identification of said infections. The skilled artisan would be unable to determine the metes and bound of the claimed invention and, thus, the claimed invention is indefinite.

Claim 13 also recites "wherein the compound of formula 1 and 2 show antifungal activity (MIC) of about 11.30 nm...". It is unclear what is meant by an antifungal activity of about 11.30 nm. The present specification discloses the compound of formula 1 has a minimum inhibitory concentration (MIC) at about 11.30 nm.

### ***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-6 are rejected under 35 USC 102(b) over Pandey et al. (Tetrahedron Letters, 1997).



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Pandey et al. teaches bis-cholamide (see page 5046, compound #4). The compound taught by the reference is encompassed by the instant claims.

13. Claims 1-10 are rejected under 35 USC 102(a) over Salunke et al. (J. Med. Chem., 2/2004).

Salunke et al. teach several steroidal dimers, including ethylenediamine-bis-cholamide and ethylenediamine-bis-deoxycholamide (see the entire article, especially page 1592, compounds #s 5 and 6). The reference also teaches (a) a process for the production of said steroidal dimers by reacting an N-succinimidyl ester solution of bile acids with a polyamine and (b) various activities of the prior art compounds such as its antiproliferative activity utilizing Hep-2 and MCF-7 cells lines (see page 1592, Scheme 1 and page 1593, Experimental Section). The compounds, compositions and methods of using and preparing taught by the reference are encompassed by the instant claims.

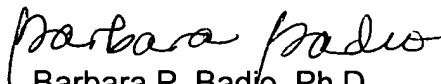
#### ***Telephone Inquiry***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
Art Unit 1617

BB  
December 5, 2005